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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,389

07/11/2008

Robert Engel

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EXAMINER

HEINCER, LIAM J

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

08/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,389	Applicant(s) ENGEL ET AL.	
	Examiner Liam J. Heincer	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of quaternary ammonium groups in the reply filed on June 21, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 26-29 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 21, 2010.

Claim Objections

Claim 15 is objected to because of the following informalities: there is a typo in claim 15 such that it reads "m 1 or 2" rather than "m is 1 or 2". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acrylic polymers having carboxyl groups, does not reasonably provide enablement for polymers of any of the claimed acrylates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The original specification teaches that the positively charged moiety is attached to the polymer via a carboxyl group (2:3-22). Additionally, the method of making the compounds of claim 1 requires the polymer to have a carboxyl group (12:20-13:12). Finally, the examples all use carboxyl functional polymers in the preparation of the claimed compound. However, claim 4 recites that the polymer can be a homopolymer of a monomer that does not contain a free carboxylic acid group. Additionally, a multitude of copolymers fall within the

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scope of claim 4 that do not contain carboxylic acid groups. It would require undue experimentation on the part of a person having ordinary skill in the art at the time of invention to attach the claimed charged moiety to these polymers absent any teaching in the original specification on how to accomplish this task.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 7-25, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Considering Claim 3: In the present instance, claim 3 recites the broad recitation "carboxyl group-containing celluloses, modified starches, chitosans, guar gums, glycans, galactans, glucans, xanthan gums, alginic acids, polymannuric acids, hyaluronic acids, polyglycosuronic and polyguluronic acids, mannans, dextrans, cyclodextrins and mixtures thereof, as well as other synthetically carboxylated or naturally occurring carboxylated polysaccharides, which may be linear or branched", and the claim also recites "preferably hyaluronic acid, gellan, xanthan, succinoglycan, pectin, chondroitine sulphate, heparan sulphate, dermatan, more preferably alginic acid and hyaluronic acid, particularly alginic acid" which is the narrower statement of the range/limitation.

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Considering Claim 5: In the present instance, claim 5 recites the broad recitation “ 10^{-1} to 10^7 monomeric units”, and the claim also recites “more preferably 20^{-1} to 10^6 , more preferably 30^{-1} to 10^5 , more preferably 40^{-1} to 10^4 most preferably greater than 1000 monomeric units” which is the narrower statement of the range/limitation.

Considering Claim 7: In the present instance, claim 7 recites the broad recitation “ C_{1-20} alkanediyl, C_{2-20} alkenediyl, C_{2-20} alkynediyl, C_{3-30} cycloalkanediyl, C_{3-30} cycloalkenediyl, C_{5-30} cycloalkynediyl, C_{7-30} aralkylenediyl, C_{7-30} alkarylenediyl and C_{5-30} arylenediyl”, and the claim also recites “preferably selected from the group consisting of C_{1-16} alkanediyl, C_{2-16} alkenediyl, C_{2-16} alkynediyl, C_{4-20} cycloalkanediyl, C_{4-20} cycloalkenediyl, C_{5-20} cycloalkynediyl, C_{7-20} aralkylenediyl, C_{7-20} alkarylenediyl and C_{6-20} arylenediyl, more preferably selected from the group consisting of straight chain C_{1-16} alkanediyl, C_{2-16} alkenediyl C_{6-16} aralkylenediyl and C_{6-16} alkarylenediyl, most preferably, R is selected from methylene, 1,2-ethylene, 1,2-propylene, 1,3-propylene, 1,2-butylene, 1,3-butylene, 1,4-butylene, 1,5-pentylene, 1,6-hexylene, 1,8-octylene, 1,10-decylene and 1,12-dodecylene” which is the narrower statement of the range/limitation.

Considering Claim 10: In the present instance, claim 10 recites the broad recitation “ C_{1-20} alkanediyl, C_{2-20} alkenediyl, C_{2-20} alkynediyl, C_{3-30} cycloalkanediyl, C_{3-30} cycloalkenediyl, C_{5-30} cycloalkynediyl, C_{7-30} aralkylenediyl, C_{7-30} alkarylenediyl and C_{5-30} arylenediyl”, and the claim also recites “preferably selected from the group consisting of C_{1-16} alkanediyl, C_{2-16} alkenediyl, C_{2-16} alkynediyl, C_{4-20} cycloalkanediyl, C_{4-20} cycloalkenediyl, C_{5-20} cycloalkynediyl, C_{7-20} aralkylenediyl, C_{7-20} alkarylenediyl and C_{6-20} arylenediyl, more preferably selected from the group consisting of straight chain C_{1-16} alkanediyl, C_{2-16} alkenediyl C_{6-16} aralkylenediyl and C_{6-16} alkarylenediyl, most preferably, R^1 is selected from methylene, 1,2-ethylene, 1,2-propylene, 1,3-propylene, 1,2-butylene, 1,3-butylene, 1,4-butylene, 1,5-pentylene, 1,6-hexylene, 1,8-octylene, 1,10-decylene and 1,12-dodecylene” which is the narrower statement of the range/limitation.

Considering Claim 19: In the present instance, claim 19 recites the broad recitation “ R^3 , R^4 and R^5 are independently selected from the group consisting of -H, C_{1-20} alkyl, C_{2-20} alkenyl, C_{2-20} alkynyl, C_{3-30} cycloalkyl, C_{3-30} cycloalkenyl, C_{4-30} cycloalkynyl, C_{7-30} aralkyl, C_{7-30} alkaryl and C_{5-30} aryl”, and the claim also recites “preferably R^3 , R^4 and R^5 are independently selected from the group consisting of -H, C_{1-15} alkyl, C_{2-15} alkenyl, C_{2-15} alkynyl, C_{3-20} cycloalkyl, C_{3-20} cycloalkenyl, C_{4-20} cycloalkynyl, C_{7-20} aralkyl, C_{7-20} alkaryl and C_{6-20} aryl, more preferably R^3 , R^4 and R^5 are independently

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selected from the group consisting of -H, straight chain C₁₋₁₀ alkyl, C₂₋₁₀ alkenyl and C₆₋₁₂ aryl, most preferably, R³, R⁴ and R⁵ are independently selected from the group consisting of methyl, ethyl, propyl, butyl, hexyl, cyclohexyl, octyl, nonyl, dodecyl, eicosyl, norbornyl and adamantyl, vinyl, propenyl, cyclohexenyl, benzyl, phenylethyl, phenylpropyl, phenyl, tolyl, dimethylphenyl, trimethylphenyl, ethylphenyl, propylphenyl, biphenyl, naphthyl, methylnaphthyl, anthryl, phenanthryl, benzylphenyl, pyrenyl, acenaphthyl, phenalenyl, aceanthrylenyl, tetrahydronaphthyl, indanyl, biphenyl, particularly methyl, ethyl, propyl and isopropyl” which is the narrower statement of the range/limitation.

Considering Claim 23: In the present instance, claim 23 recites the broad recitation “R⁶, R⁷ and R⁸ are independently selected from the group consisting of -H, C₁₋₂₀ alkyl, C₂₋₂₀ alkenyl, C₂₋₂₀ alkynyl, C₃₋₃₀ cycloalkyl, C₃₋₃₀ cycloalkenyl, C₄₋₃₀ cycloalkynyl, C₇₋₃₀ aralkyl, C₇₋₃₀ alkaryl and C₅₋₃₀ aryl”, and the claim also recites “preferably R⁶, R⁷ and R⁸ are independently selected from the group consisting of -H, C₁₋₁₅ alkyl, C₂₋₁₅ alkenyl, C₂₋₁₅ alkynyl, C₃₋₂₀ cycloalkyl, C₃₋₂₀ cycloalkenyl, C₄₋₂₀ cycloalkynyl, C₇₋₂₀ aralkyl, C₇₋₂₀ alkaryl and C₆₋₂₀ aryl, more preferably R³, R⁴ and R⁵ are independently selected from the group consisting of -H, straight chain C₁₋₁₀ alkyl, C₂₋₁₀ alkenyl and C₆₋₁₂ aryl, most preferably, R⁶, R⁷ and R⁸ are independently selected from the group consisting of methyl, ethyl, propyl, butyl, hexyl, cyclohexyl, octyl, nonyl, dodecyl, eicosyl, norbornyl and adamantyl, vinyl, propenyl, cyclohexenyl, benzyl, phenylethyl, phenylpropyl, phenyl, tolyl, dimethylphenyl, trimethylphenyl, ethylphenyl, propylphenyl, biphenyl, naphthyl, methylnaphthyl, anthryl, phenanthryl, benzylphenyl, pyrenyl, acenaphthyl, phenalenyl, aceanthrylenyl, tetrahydronaphthyl, indanyl, biphenyl, particularly methyl, ethyl, propyl and isopropyl” which is the narrower statement of the range/limitation.

Considering Claim 31: In the present instance, claim 31 recites the broad recitation “N-hydroxysuccinimide, N-hydroxybenzotriazole, nitrate, sulfate, bisulfate, phosphate (mono-, bi-, or triphosphate), carbonate, bicarbonate, acetate, tosylates, mesylates, brosylates, and halides including chloride, bromide, and iodide”, and the claim also recites “preferably tosylate” which is the narrower statement of the range/limitation.

Considering Claim 3: Claim 3 contains an improper markush group. The scope of a Markush group must be closed. The language "as well as other synthetically carboxylated and naturally occurring

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carboxylated polysaccharides" opens the scope of the claim as they occur outside the Markush group and thus reopen the scope of the claim.

Considering Claim 14: The amendment to claim 14 removes the recitation of which variable the range refers to. As such, the scope of the claim is unclear. For the purpose of further examination, the claim is being interpreted as referring to m.

Considering Claim 20: Claim 20 recites the limitation "the polysaccharide" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

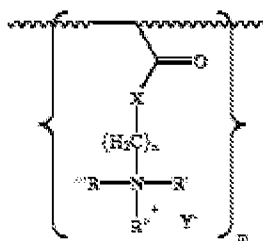
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-8, 10, and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Perrault et al. (US Pat. 6,039,940).

Considering Claims 1, 4-8, 10, and 14-17: Perrault et al. teaches an antimicrobial polymer (Title)



having the structure

where n is 2 or 3, R', R'', and R''' are C₁₋₁₆ alkyl, aryl

arylamine, alkylamine, alkaryl or arakyl, m is greater than 50,000 and y is a counterion (claim 1).

Considering Claim 18: Perrault et al. teaches the counter ion as being a halide or sulfite (Claim 10).

Considering Claim 19: Claim 6, from which claim 19 depends, requires R² to be -H. As R³, R⁴, and R⁵ are only present in embodiments where R² is not -H, the instant claim limitations further limiting R³, R⁴, and R⁵ does not provide patentability to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

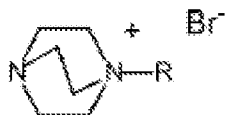
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namikoshi et al. (US pat. 4,877,617) in view of Abel et al. (Carbohydrate Research 337 (2002) 2495-2499) as evidenced by Cohen et al. (Tetrahedron Letters 39 (1998) 8617-8620) and Hardy (US Pat. 6,022,556).

Considering Claims 1-3, 5-7, 10, 12-18, 20-25: Namikoshi et al. teaches a carboxyl functional polysaccharide that is preferably alginic acid that has been reacted with a quaternary ammonium compound (2:40-3:2). Namikoshi et al. teaches the alginic acid as having a molecular weight of 10,000 to 500,000 (3:48-55).

Namikoshi et al. does not teach covalently bonding the quaternary ammonium compound with the alginic acid. However, Abel et al. teaches covalently attaching a quaternary ammonium compound to a polysaccharide (pg. 2495). Abel et al. teaches the quaternary ammonium compound



as being
2496).

where R is a straight chain alkyl having 8 to 18 carbon atoms (pg.

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Cohen et al. teaches that these compounds can be further functionalized with alkylhydroxy groups (pg. 8617) and Hardy teaches that alcohols will react with alginic acid to form ester groups (abstract). Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. See MPEP §2141. A person having ordinary skill in the art at the time of invention would have used the methods described in the prior art to attach functional groups that will react with the carboxylic acid groups of the polysaccharide.

Namikoshi et al. and Abel et al. are analogous art as they are concerned with the same field of endeavor, namely polysaccharides functionalized with quaternary nitrogens to provide antimicrobial properties. It would have been obvious to a person having ordinary skill in the art at the time of invention to have covalently bonded the compound of Abel et al. to the polysaccharide of Namikoshi et al., and the motivation to do so would have been, as Abel et al. suggests, covalent bonding prevents dissociation of the quaternary ammonium compound (pg. 2495) and the compounds of Abel et al. are not consumed during use (pg. 2497).

Considering Claims 8, 9 and 11: Namikoshi et al. and Abel et al. are silent towards whether all the R or R¹ groups are the same or a mixture. However, the references teach a range of alkyl groups that can be used for variables. “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It would have been obvious to a person having ordinary skill in the art at the time of invention to have used a mixture of compounds with different numbers of carbon atoms in the hydrocarbon chains as they are both taught to have utility in antimicrobial compounds.

Considering Claim 19: Claim 6, from which claim 19 depends, requires R² to be -H. As R³, R⁴, and R⁵ are only present in embodiments where R² is not -H, the instant claim limitations further limiting R³, R⁴, and R⁵ does not provide patentability to the claims.

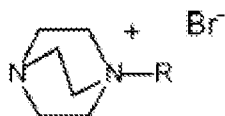
Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namikoshi et al. (US pat. 4,877,617) in view of Abel et al. (Carbohydrate Research 337 (2002) 2495-2499) as

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evidenced by Cohen et al. (Tetrahedron Letters 39 (1998) 8617-8620) and Hardy (US Pat. 6,022,556).

Considering Claim 30: Namikoshi et al. teaches a carboxyl functional polysaccharide that is preferably alginic acid that has been reacted with a quaternary ammonium compound (2:40-3:2). Namikoshi et al. teaches the alginic acid as having a molecular weight of 10,000 to 500,000 (3:48-55).

Namikoshi et al. does not teach covalently bonding the quaternary ammonium compound with the alginic acid. However, Abel et al. teaches covalently attaching a quaternary ammonium compound to a polysaccharide (pg. 2495). Abel et al. teaches the quaternary ammonium compound



as being where R is a straight chain alkyl having 8 to 18 carbon atoms (pg. 2496).

Cohen et al. teaches that these compounds can be further functionalized with alkylhydroxy groups (pg. 8617) and Hardy teaches that alcohols will react with alginic acid to form ester groups (abstract). Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. See MPEP §2141. A person having ordinary skill in the art at the time of invention would have used the methods described in the prior art to attach functional groups that will react with the carboxylic acid groups of the polysaccharide.

Namikoshi et al. and Abel et al. are analogous art as they are concerned with the same field of endeavor, namely polysaccharides functionalized with quaternary nitrogens to provide antimicrobial properties. It would have been obvious to a person having ordinary skill in the art at the time of invention to have covalently bonded the compound of Abel et al. to the polysaccharide of Namikoshi et al., and the motivation to do so would have been, as Abel et al. suggests, covalent bonding prevents dissociation of the quaternary ammonium compound (pg. 2495) and the compounds of Abel et al. are not consumed during use (pg. 2497).

Considering Claim 31: Namikoshi et al. does not teach the ammonium compound as having one of the claimed leaving groups. However, Abel et al. teaches that hydroxyl groups can be activated with tosylate groups (pg. 2496). It would have been obvious to a person having ordinary skill in the art at the time of invention to have activated the hydroxyl groups of the ammonium compound, and the

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motivation to do so would have been, as Abel et al. suggests, increased the reactivity of the hydroxyl group.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO Form 892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/

Supervisory Patent Examiner, Art Unit 1796

LJH

August 3, 2010